

Testimony of Dennis Johnson, Director of Health, on February 27, 2009  
Regarding proposed Bill no. 5635, "An Act Concerning the Administration of Fetal Ultrasound Procedures"

---

My name is Dennis Johnson I am the Director of Health for the Town of Guilford. Last fall our office received an inquiry from a resident regarding the opening of a local ultrasound business. Upon investigation I discovered that the business is part of a growing trend across the country aimed primarily at expectant parents. These businesses, sometimes known by the commercial franchise names of "Fetal Photos" "Tiny Perspectives" "Sneak Previews" "Womb with a View" are not part of a licensed medical facility but rather private-commercial operation commonly referred to as ultrasound boutiques. They are classified as entertainment ultrasounds and are prohibited from giving out medical or diagnostic information. Their main service is to produce, for expectant parents, non-medical or entertainment fetal images created by 2, 3 or 4-dimensional ultrasound imaging equipment. Conventional ultrasounds produce two dimensional grainy black and white photos which expectant parents take these away from their obstetrician's office. Ultrasound boutiques now offer 3D images, and even movie images of the child. The high-tech ultrasound machines utilized by these boutiques are capable of producing Doppler imaging so clear that the fetus can be observed yawning, thumb sucking or swallowing. These images are often transferred into DVD or VHS format to create digital keep-sake scans.

Currently, ultrasound technicians or sonographers in Connecticut that operate ultrasound equipment independent of licensed medical facilities are not required to be licensed or even credentialed by the State Health Department. There are no minimum educational requirements needed to perform the scan. However, ultrasound sonographers that work in a physician's office are required to be board certified because here, an ultra sound is a prescriptive procedure. This is

not to say, however, that independent sonographers have not had prior experience or board certification while working in a medical facility.

The FDA has issued warnings about entertainment ultra sounds. Although there is no strong evidence that they are harmful there is no evidence that they are not harmful. Several studies have revealed possible developmental links to excessive use such as delayed speech or neurological development.

The FDA has said: "Although there is no evidence that these physical effects can harm the fetus, public health experts, clinicians and industry agree that casual exposure to ultrasound, especially during pregnancy, should be avoided." And there are also worries about how a commercial scanner would deal with finding a medical abnormality in the baby.

Ultrasonic fetal scanning, from a medical standpoint, generally is considered safe if properly used when information is needed about a pregnancy. Still, ultrasound is a form of energy, and even at low levels, laboratory studies have shown it can produce physical effects in tissue, such as jarring vibrations and a rise in temperature. Although there is no evidence that these physical effects can harm a fetus, the FDA says the fact that these effects exist means that prenatal ultrasounds cannot be considered completely innocuous. The US Food and Drug Administration has made a strong recommendation against commercial ultrasound movies, and states that; "Mothers leave falsely reassured and then they miss their scheduled ultrasounds with their doctor," says ultrasound expert Jacques Abramowicz at Rush University Medical Center, Chicago, Illinois. He says that this has resulted in some serious birth abnormalities going undetected in the womb. Obstetricians use ultrasound at a very low power level to check the size, location, number, and age of fetuses, the presence of some types of birth defects, fetal

movement, breathing, and heartbeat. When ultrasound is used by a qualified clinician to check for this kind of information, the FDA says the medical benefit far outweighs any risk. As more advanced ultrasound technologies (usually using higher ultrasound intensities) become available, greater numbers of expectant mothers and their families are requesting fetal keepsake videos and portraits for souvenirs. Fetal keepsake videos are viewed as problems because there are no medical benefits derived from the exposure. Further, there is no control on how long a single imaging session will take or how many sessions will occur. The FDA notes that some video companies have been known to use the ultrasound machine on higher energy exposures for as long as an hour to get the pictures. The procedure should always be done at the lowest possible energy output and for the least amount of time. Exposure to ultrasound for longer than the time specified by the FDA for fetal monitoring could pose a potential risk to the health of the mother and her developing fetus.

Some companies make it clear that they are not providing diagnostic ultrasounds, but those that don't may wrongly give women the impression that their ultrasound examination will identify problems.

The FDA and the American Institute of Ultrasound in Medicine (AIUM), which also strongly discourages the non-medical use of ultrasound, have concerns that women are being wrongly reassured by commercial sonograms. Women may misinterpret the studio ultrasound as a medical examination, thus giving them a false sense of security. Inaccurate findings by the sonographer may also cause them to undergo unnecessary follow-up tests.

I am aware that the sponsors of this bill are offering new, substitute language that will require fetal ultrasound procedures only be administered to a patient when deemed medically necessary

by and ordered by a medical professional. By permitting ultrasounds only through prescriptive order or by a medical professional you will ensure that pregnant women will receive professional care that contributes to their health and to the health of their babies. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient. I support the approach of this bill and urge the committee to adopt it.